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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,583	06/02/2006	Allan Mishra	MISHRA.021NP	6996

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
AFREMOVA, VERA	

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
06/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/581,583	MISHRA, ALLAN	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-10 and 46-51* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,10, 46-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/02/06;7/25/07;8/29/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of the Group II, drawn to a method of making a first product comprising platelets and carrier (claim 8), in the reply filed on 3/11/2009 is acknowledged. Applicant's election is made with traverse with respect to the restriction requirement between the Group II (claim 8) and the Group V (new claim 50, drawn to a method of making a product comprising platelets and a transdermal patch carrier). Upon applicant's request the Group II and Group V have been rejoined and restriction requirement between these two groups has been withdrawn.

Claim 9, being drawn to a method of using a product (group I), has been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention without traverse (3/02/2009; 12/17/2008), there being no allowable generic or linking claim.

Claims 8, 10 and 46-51 are under examination in the instant office action.

Claim Objections

Claims 8, 10 and 46-51 are objected to because of the following informalities: Claim 8 does not have a preamble and, thus, improper. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 8, 10, 46-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 does not have a preamble and, thus, indefinite with regard to the final result and/or indented effect/purpose. Claim has been interpreted as being directed to a method of making a composition comprising platelets and a pharmaceutical carrier.

Claim 50 recites " a composition comprising the platelets" (line 3) in the method of making/forming a composition with the platelets (claim 8, line 5). Thus, claim 50 is indefinite and/or it lacks antecedent basis with regard to platelets. It is unclear, what are the differences between several preparations with platelets, if any. Claim 50 extends the claimed invention rather than further limits it.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,599,558 (Gordinier et al).

Claims are directed to a method of making a composition wherein the method comprises steps of extracting blood from a patient, concentrating platelets from the blood and combining the platelets with an enhancer and a pharmaceutical carrier suitable for topical application to skin. Some claims are further drawn to the carrier being collagen.

US 5,599,558 (Gordinier et al) discloses a method of making a composition with platelets (entire document) including composition intended for skin application and wrinkle treatment (col. 5, lines 30-32) wherein the method comprises steps (col. 8, example 1) of extracting blood

from a patient, concentrating platelets from the blood or making platelets rich plasma (PRP) and step of combining the platelets with an enhancer or buffer, for example, and a pharmaceutical carrier suitable for topical application to skin, for example: collagen. Thus, the cited reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 10 and 46-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,599,558 (Gordinier et al), US 5,993,804 (Read et al) and US 5,733,571 (Sackler).

Claims are directed to a method of making a composition wherein the method comprises steps of extracting blood from a patient, concentrating platelets from the blood and combining the platelets with an enhancer and a pharmaceutical carrier suitable for topical application to skin. Some claims are further drawn to the carrier being collagen. Some claims are further drawn to the carrier being a transdermal patch and/or to steps of combining the platelets-containing composition with components of the transdermal patch.

US 5,599,558 (Gordinier et al) is relied upon as explained above for the disclosure of a method of making a composition with platelets (entire document) including composition intended for skin application and wrinkle treatment (col. 5, lines 30-32) wherein the method comprises steps (col. 8, example 1) of extracting blood from a patient, concentrating platelets from the blood or making platelets rich plasma (PRP) and step of combining the platelets with an

enhancer or buffer, for example, and a pharmaceutical carrier suitable for topical application to skin, for example: collagen. The disclosed the platelets-containing compositions are suitable to topical application and they are made in a form of liquid or paste. Thus, the cited US 5,599,558 (Gordinier et al) is silent about incorporation of solid support materials or components of the transdermal patch into platelets-containing compositions.

However, US 5,993,804 teaches combining solid support materials including adhesives with platelets-containing compositions as intended for topical application and for healing skin wounds, for example: col. 11, lines 50-67 and col. 4, lines 21-40.

Furthermore, US 5,733,571 is relied upon to demonstrate that the use of transdermal patches is well known for delivery of medicinal agents and that the methods of preparing the transdermal patches include steps of combining components including permeable membrane (diffusion layer), impermeable membranes (backing and/or blocking layers) and adhesives with the active agent delivery matrix, for example: col. 5, lines 31-51.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the method of US 5,599,558 (Gordinier et al) by adding steps of incorporating platelets into transdermal patches with a reasonable expectation of success in providing composition suitable for skin application and wrinkle treatment because with platelets-containing compositions are combined with support materials for topical applications and the use of transdermal patches is well known in the art for delivery of various medicinal agents. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

June 3, 2009

/Vera Afremova/

Primary Examiner, Art Unit 1657